Application No. 10/666,886 Amendment dated August 18, 2009 Office Action of February 20, 2009

## **REMARKS**

Claims 1-3 and 5-11 are pending. Claims 1, 2 and 5 are amended. Claims 3 and 4 are withdrawn. No new matter is added.

Objections

The Examiner has objected to claims 1-3 and 5-11 for the recitation of the term "vaccine." Claim 1 has been amended to delete the term "vaccine" and claim 3 has been withdrawn.

## Rejections Under 35 U.S.C. 102(b)

Claims 1-3 and 5-11 are rejected under 35 U.S.C 102(b) in view of Hoo (U.S. 5,891,432.)

The Examiner asserts that instant claims 1-3 and 5-11 are anticipated by and non-novel over the Hoo et al. reference. The Examiner supports this conclusion as follows: "[i]n the composition of Hoo, the antigen and the fusion polypeptide are bounded and unbounded together [Claim 1 and claim 12, in particular] (see page 4 of the Office Action)."

Applicants disagree with and traverse this rejection.

Applicants submit that for a determination of anticipation to be proper, the prior art reference must disclose each and every limitation of the claim. *Atlas Powder Company et al. v. IRECO, Incorporated et al.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

Claim 1 and dependent claims 2 and 5-11 recite "A composition suitable for administration to a subject, said composition comprising a virus or a cell and a fusion polypeptide, said fusion polypeptide comprising a first amino acid sequence which comprises a cell-surface binding moiety and a second amino acid sequence comprising a ligand for a cell surface polypeptide of a leukocyte, wherein said vaccine composition includes said <u>fusion polypeptide bound</u> to said virus or said cell and includes said <u>fusion polypeptide which is not bound</u> to said virus or said cell.

As disclosed in Examples 18 and 19 of the instant application, compositions useful according to the claimed invention comprise bound and free fusion polypeptide (see for example page 197, lines 4-7 wherein it is stated that "[t]he cells were irradiated at 3500 rads from a <sup>137</sup>Cs source. 8 week-old female C57BL/6 mice were anesthetized by metofane inhalation and vaccinated subcutaneously in the left inguinal fold with or 1.times.10.sup.6 cells in 0.25 ml RPMI, along with a total of 1 ug GM-CSF-HA1 (including bound and free fusion polypeptide))."

Both claim 1, and dependent claim 12 of the Hoo et al. reference, require only a fusion protein which is "membrane bound," i.e. bound to the recited cell. However, the Hoo et al. reference does not teach or even suggest that the composition of Hoo et al. further comprises a fusion polypeptide which is **not bound** to the cell.

Applicants assert that the Hoo et al. reference teaches a "cellular vaccine having a membrane-bound fusion protein that includes a non-antibody immunomodulatory molecule operatively fused to a heterologous membrane attachment domain (see for example column 3, lines 10-13). Hoo et al. also disclose at column 3, lines 27-30 that "[a] vaccine of the invention contains one or more such non-antibody immunoregulatory molecules in membrane bound form."

All of the all of the instantly pending claims expressly recite and require that the claimed composition comprise a population of molecules of the fusion polypeptide which are **not** bound to the recited cell or virus, **in addition to** the molecules of fusion polypeptide which **are** bound to the cell or virus. This is a mandatory element of the invention which is completely lacking in the teachings of Hoo et al.

In view of all of the above, the '432 patent clearly does not teach or suggest all of the requisite elements of the pending claims. Because of this deficiency, Hoo et al cannot be used as the basis for a rejection under 35 U.S.C. 102(b).

Applicant respectfully requests reconsideration and withdrawal of the rejection.

## Obviousness-type Double Patenting

Application No. 10/666,886 Amendment dated August 18, 2009 Office Action of February 20, 2009

The Office Action states that the instant claims are rejected under the judicially created doctrine of obviousness type double patenting in view of several copending applications. Upon notification of otherwise allowable subject matter in the instant case, Applicants will timely file a terminal disclaimer effective to obviate the double patenting rejection.

Applicant submits that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney/agent of record.

Dated: August 18, 2009

Respectfully submitted,

Electronic signature: /Elizabeth N. Spar/
Elizabeth N. Spar
Registration No.: 45,123
EDWARDS ANGELL PALMER & DODGE
LLP
P.O. Box 55874
Boston, Massachusetts 02205
(617) 239-0614
Attorneys/Agents For Applicant